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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,597	04/30/2001	Antoni P. Tomsia	IB-1627	3236
8076	7590	02/24/2004	EXAMINER	
LAWRENCE BERKELEY NATIONAL LABORATORY ONE CYCLOTRON ROAD, MAIL STOP 90B UNIVERSITY OF CALIFORNIA BERKELEY, CA 94720			SPERTY, ARDEN B	
		ART UNIT	PAPER NUMBER	
		1771		

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/845,597	TOMSIA ET AL.
	Examiner Arden B. Sperty	Art Unit 1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 November 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,5,8-12,20-28 and 30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3,5,8-12,20-28 and 30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

**FINAL OFFICE ACTION  
FOLLOWING RCE**

Objection to the Specification has been withdrawn, as the new matter was cancelled per Applicant's response.

Rejection of claims 25 and 27 made under 35 USC 112 have been withdrawn, as the numerical ranges in the claims have been changed.

Rejections made under 35 USC 102 and 35 USC 103 remain unchanged and are restated herein, followed by Examiner's response to Applicant's arguments.

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 111(b)(1) as follows:

Section 35 USC 111(b)(1) states:

Such application shall include- (A) a specification as prescribed by the first paragraph of section 112 of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's claim for priority to Provisional Application 60/201,556 is denied.

The provisional application contains a collection of articles which are not seen to provide support for the claimed invention. It should be noted that the IDS designates three articles as Prior Art which are also included as part of the "Provisional Application." The inventive entity of at least one article is not the same as that of the present invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by the article titled “HA-bioactive glass composites: High temperature reactivity and ‘in-vitro’ behavior” by Paz, et al.

Regarding claim 1, the reference teaches a multilayered article (see text of page 1733 and Figures 6 and 7) comprising a Ti or Ti alloy substrate (see line 6 of abstract) and a first layer comprising a glass of the claimed composition (see page 1729, first paragraph under “Materials and Methods), further comprising HA in an amount of 25% (up to 50%) (page 1729, last paragraph).

Regarding claim 8, the substrate is Ti or Ti alloy (abstract line 6).

Regarding claim 23, the reference teaches the amount of SiO<sub>2</sub> within the claimed range (page 1729, first paragraph under “Materials and Methods”).

Claims 1, 3, 5, 8-12, and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000.

Regarding claim 1, the reference teaches a multilayer article (see bottom of page 16) comprising a metal substrate (see abstract), and a first layer comprising the claimed glass

composition (Table I, samples 6P55, 6P57, 6P61) and an amount of HA within the claimed range (bottom of page 16).

Regarding claim 3, the reference teaches the article of claim 1 having multiple layers (intermediate layers) (page 19, lines 1-8) comprising a glass composition as defined in claim 1 (see Table I).

Regarding claim 5, the reference teaches the article of claim 3 having a first intermediate layer having a HA concentration of 0%, a second intermediate layer having a HA concentration of 20%, and a first layer having a HA concentration of 40% (page 19, lines 1-8).

Regarding claim 8, the reference teaches the article of claim 1 wherein the substrate is Ti-6Al-4V (see abstract).

Regarding claims 9-12, the reference teaches the claimed glass compositions on a substrate of Ti-6Al-4V and HA concentrations meeting the claim limitations (Table I and bottom of page 16).

Regarding claim 20, the reference discloses a multilayer article comprising a Ti6Al4V substrate (see abstract) having a first layer and 2 intermediate layers, the layers comprising the claimed glass composition (see Table I) and an amount of HA within the claimed range (bottom of page 16).

Regarding claims 21 and 23, Table I shows the SiO<sub>2</sub> content of samples 6P55 and 6P57 to be within the claimed range.

Regarding claims 22 and 24, the bottom of page 16 teaches n=2.

Regarding claims 25 and 27, Table I shows the SiO<sub>2</sub> content of sample 6P61 to be within the claimed range.

Regarding claims 26 and 28, the bottom of page 16 teaches n=2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000 as applied above, and further in view of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," by Gomez-Vega et al, published 1999.

While the 2000 Gomez-Vega reference discloses a multilayer article as presently claimed wherein n=2 (having a second intermediate layer between the first intermediate layer and the substrate), the reference is silent with respect to a SiO<sub>2</sub> gradient wherein the highest SiO<sub>2</sub> concentration is closest to the substrate. The reference further states that a desired quality in the multilayer article is good adhesion of the coatings to metal (Introduction, the paragraph that spans the bottom of page 15 to the top of page 16). The 1999 Gomez-Vega reference teaches a multilayer article having a metal substrate, glass layers having the claimed composition, and an outer layer having HA particles embedded therein, further having an SiO<sub>2</sub> gradient wherein the highest SiO<sub>2</sub> concentration is closest to the substrate to achieve excellent adhesion to the metal substrate. Therefore, since excellent adhesion to the substrate is a desirable quality in the multilayer article of the 2000 Gomez-Vega reference, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to combine the multilayer article having an HA gradient according to the 2000 Gomez-Vega reference with the 1999 Gomez-Vega reference to achieve excellent adhesion to the metal substrate.

***Response to Arguments***

Applicant's arguments filed 21 November 2003 have been fully considered but they are not persuasive.

Regarding Applicant's insistence that arguments have gone unanswered, the Examiner has made every effort to respond to all of Applicant's arguments and concerns.

Applicant's repeated insistence that the examiner point to the deficiencies in the provisional application is without merit. The rejections presented above are complete.

Applicant argues that the provisional application does provide support for the claim for priority and that the instant claims comply with 35 USC 112 first paragraph. Applicant has pointed to several passages in an effort to show support for isolated elements of the present claims. Those passages are from different unconnected documents.

The documents in the provisional application have been carefully reviewed. Present claim 1 requires a metallic article comprising a metal substrate and a layer having an inner and outer surface and comprising a specific glass composition and up to 50 wt% HA particles. It is the position of the examiner that "up to" includes zero so the HA particles are optional. A reading of the present specification indicates this position is accurate. The documents alone or in combination are not seen to teach this combination. The Pazo document entitled "HA-bioactive

“glass composites” was applied against claims 1, 8 and 23 under 35 USC 102(b) however the article is to a different inventive entity. Therefore, priority is denied.

Applicant’s argument regarding new matter added to the specification is moot pursuant to cancellation of claim 29.

Applicant’s argument against the 35 USC 102(b) rejection of claims 1, 8 and 23 over “HA-bioactive glass composites” is not persuasive. Applicant’s argument is that Pazo does not teach a multilayer article on the Ti-substrate, however the reference teaches the layering of the claimed glass composition on a metal alloy.

Applicant argues that the amendment to claim 1 overcomes the 35 USC 102(b) rejection over “Silicate Glass coatings on Ti-based implants.” This is not so. The claim still requires that the HA particles are present in an amount “up to 50 wt%,” a range which includes 0%.

Regarding the publication date of the “Glass-Hydroxyapatite coating on titanium-based implants” article, the letter from The American Ceramic Society has been considered and the rejection still stands based on the Society’s disclosure of publication in February 2000.

Applicant’s arguments regarding the 35 USC 103 rejection of claim 30 has been considered, however in view of the above remarks, that rejection is also seen to be valid and is herein maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arden B. Sperty whose telephone number is (571) 272-1543. The examiner can normally be reached on M-Th, 08:00-16:00.

Art Unit: 1771

If attempts to reach the examiner by telephone are unsuccessful SPE Deborah Jones can be reached at (571) 272-1535. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

*Arden B. Sperty*  
Arden B. Sperty  
Examiner  
Art Unit 1775

*Deborah Jones*  
DEBORAH JONES  
SUPERVISORY PATENT EXAMINER